Decision Memo for Electrical Stimulation for Fracture Healing (CAG-00043N)

Decision Summary

Amend Coverage Issues Manual section 35-48 to include:

Fracture nonunion is considered to exist only when serial radiographs have confirmed that fracture healing has ceased for three or more months prior to starting treatment with the electrical osteogenic stimulator. Serial radiographs must include a minimum of two sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days.

Back to Top

Decision Memo

TO: File: CAG-00043
Electrical Stimulation for Fracture Healing

FROM:

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RE: National Coverage Policy Revision

DATE: November 9, 1999

This memo serves four purposes: (1) outlines the description of bone physiology and fracture nonunion; (2) reviews the history of Medicare's coverage policies on electrical stimulation for fracture healing; (3) analyzes the relevant scientific data related to electrical stimulation for fracture healing; (4) delineates the reasons supporting a revision of Coverage Issues Manual section 35-48 to change the time frame definition of nonunion.

Described as the body's "living framework," the human skeleton - comprised of 206 bones -provides protection for the vital organs, allows adequate movement against the forces of gravity, stores minerals and salts necessary for vital function, and produces red blood cells necessary for cellular oxygenation. The skeletal system is divided into two major subdivisions, the axial and the appendicular skeletons. The axial skeleton consists of the skull, vertebral column, and the thorax. The appendicular skeleton consists of the shoulder girdle and bones of the upper extremity and the pelvis and bones of the lower extremity. Typically, bones have been classified into four major areas. The primary bones belonging to these classes are listed below:

Table 1:

LONG BONES	SHORT BONES	FLAT BONES	IRREGULAR BONES
clavicle, humerus, radius, ulna, femur, tibia, fibula, metacarpal and metatarsal	Bones of the carpus and tarpus	occipital, parietal, frontal, nasal, lachrymal, vomer, scapula, os innominatum, sternum, ribs, patella	vertebrae, sacrum, coccyx, temporal, sphenoid, ethmoid, malar, superior and inferior maxillary, palate, inferior turbinated, hyoid

Bone is comprised of two particular types of tissue, compact (cortical bone) and cancellous (cancellous or trabecular bone). Cortical bone is described as dense, compact bone, while cancellous bone is described as spongy, porous-like bone typically found at the distal and proximal ends of long bones. Although the quantity of these two types of tissue differs dependent on the specific bone identified, and the structural composition of these two tissue types differs, the basic cellular structure of both is the same.

Normal bone healing consists primarily of five stages and is dependent on mechanical factors, biological factors, and bioelectric factors. These stages include:

- Inflammation/hematoma, where callus formation occurs within days of injury;
- The osteoblastic migratory stage and the beginnings of the viscoelastic bridge (approximately 2 weeks post injury);
- Calcification of the fibrocartilage and bridging of the fracture gap (approximately 4 weeks post injury);
- Acceleration of the calcification process, with fibrocartilage replaced by fibrous bone and revascularization at the fracture site (approximately 8 weeks post injury); and
- Rigid bone development and return of stasis between osteoblasts and osteoclasts (2 months to 2 years post injury).

Most patients who sustain bone fractures and who receive appropriate medical therapy heal with conventional treatment modalities such as splinting, casting, or fixation (either internal/external). However, secondary to certain specific causes, the normal reparative process of bone healing can be affected.

These causes include but are not limited to: infection at the fracture site, inadequate blood supply to the affected area, excessive movement between bone fragments, interposition of soft tissue between the bone fragments, loss of apposition between bone fragments, destruction of bone, presence of corroding metal, and dissolution of the fracture hematoma by synovial fluid.[1]

Other systemic factors affecting normal bone healing include the patient's metabolic and nutritional status, general health, and activity level. These factors are particularly relevant to the elderly Medicare population and can predispose these patients to an increased incidence of delayed or absent healing. Furthermore, the incidence of delayed or absent healing has increased as the treatment options for fractures previously requiring amputation has led to an increase in the possibility of new problems in fracture union and rehabilitation.

Delayed Union

Although definitions of delayed union and nonunion vary widely in the published medical literature, in general union is considered delayed when healing has not advanced at the "average" rate for the location and type of fracture. Delayed union is often characterized by slow radiographic progress and continued mobility and pain at the fracture site. Delayed union differs from nonunion in that in the former, there are no indications that union will fail, while in the latter, there are no longer any visible signs that union will occur.

Nonunion

In general, nonunion occurs when characteristic changes are observed radiographically and clinically which suggest that fracture healing has ceased and additional intervention is necessary as the standard for treatment. Nonunions can be identified by fibrocartilage which remains in the fracture gap, impeding vascularization and subsequent calcification, and can present on radiographs as sclerotic bone ends around a fracture gap with a visible fracture line.

Typical signs of nonunion that have been utilized in scientific studies are: Clinically – motion or pain at the fracture site and local tenderness, and Radiographically – anteroposterior (AP) and lateral radiographs performed at frequent intervals showing no progression of healing, (healing usually defined as cortical and/or trabecular bridging with major modifications of the radiolucent gap).

Nonunions are typically subdivided in two principle categories - hypertrophic and atrophic - according to the viability of the ends of the affected bone fragments. Hypertrophic nonunions are capable of biological reaction and have the ability to spontaneously heal, while atrophic nonunions do not.

Treatment of Nonunions

Currently there are a large number of surgical and nonsurgical treatment modalities available for the treatment of delayed unions and nonunions. These include immobilization and/or casting, open or closed reduction, compression plates, pins, screw fixation, intramedullary rods, bone grafts, and electrical stimulation.

Historically, nonunion has been treated with bone grafting procedures, although more recently other techniques have been utilized in order to minimize the risks inherent in bone graft operations. In the elderly Medicare population, noninvasive techniques for nonunion treatment are particularly important as they can be utilized to avoid the potential complications resulting from major surgery.

In general, the method of treatment is best determined on a case by case basis, dependent on fracture location and patient characteristics.

Medicare's Coverage Policies on Electrical Stimulation for Fracture Healing

Description of Electrical Stimulation for Fracture Healing

It has been suggested that mechanical loading may induce signals that initiate the bone remodeling process. This hypothesis predicts that bone is responsive to extremely low-energy endogenous electric fields and suggests that bone remodeling can be regulated by exogenous electromagnetic fields.[2]

It has also been suggested that electromagnetic fields (EMFs) may have direct biological effects on endochondrial cells. These include promotion of decreased synthesis of growth factors caused by disruption of endosteal bone formation at the fracture site and enhanced expression of bone morphogenetic protein-2 (BMP-2) and BMP-4.[3]

Three primary electrical and electromagnetic methods are used in the treatment of nonunions. These include invasive, semi-invasive, and noninvasive devices. Noninvasive devices that use pulsed electromagnetic fields (PEMFs) designed to induce electrical currents to replace those lost in the absence of normal mechanical loading were approved for human use by the Food and Drug Administration (FDA) in 1979. These devices typically use conductive or inductive coupling utilizing treatment coils placed externally around the fracture sight for a certain time period each day. Weak pulsing electrical currents created by the low energy electromagnetic field produced by passing current through the treatment coil are applied at the fracture site. Length of treatment is dependent on patient characteristics, fractures location, and physician determination.

Device Manufacturers

Currently there are four primary manufacturers of noninvasive electrical bone growth stimulators in the United States:

1. Electro-Biology, Inc. EBI manufactures the EBI Bone Healing System® and FLX Flexible Treatment Coil. This system is available in three different models and utilizes a battery charger cradle, control unit, and FLX® flexible treatment coil. Required FDA labeling for this device indicates its use for "the treatment of fracture nonunions, failed fusions, and congenital pseudarthrosis in the appendicular system." System configuration is dependent on the patient profile and physician prescription.
2. Orthologic, Inc. Orthologic manufactures the Orthologic 1000® – Single Coil (OL1000SC) and Dual Coil (OL1000) bone growth stimulators. These devices are available in a number of models designed for application at specific fracture locations. Both devices utilize Combined Magnetic Field (CMF) technology, which combines dynamic magnetic fields and static magnetic fields for treatment. The OL1000® is indicated for the noninvasive treatment of an established nonunion acquired secondary to trauma, excluding vertebrae and all flat bones.
3. Orthofix, Inc. Orthofix manufactures the Physio-Stim Lite. This system is available in a variety of models with different transducer capabilities dependent on the fracture site being stimulated. It is indicated for all nonunions excluding vertebrae and flat bones.
4. Biolectron, Inc. Bioelectron manufactures the Orthopak Bone Growth Stimulator. This system utilizes capacitive coupling to produce a time-varying electric field, which can be applied to a large volume of tissue and bone at the fracture site. It is indicated for all nonunions excluding flat bones.

History of Coverage Process

Medicare coverage for electrical stimulation for fracture healing has been in effect since September 15, 1980 (Coverage Issues Manual 35-48). Initial coverage was limited to **noninvasive** devices for the treatment of nonunion of long bone fractures, failed fusion, and congenital pseudarthroses.

Coverage of electrical stimulation for fracture healing was based on an assessment done by the National center for Health Care Technology. This assessment analyzed the findings of a clinical trial undertaken by EBI as part of their premarket approval application (PMA) that involved 308 patients (318 fractures) which found an overall "success" rate (functional union) of 77 percent for patients with nonunion, delayed union, failed fusion, and congenital pseudarthrosis. Additionally, expert opinion from a workshop convened by the National Institute of Arthritis, Metabolism and Digestive Diseases (NIAMDD) and the American Academy of Orthopaedic Surgeons entitled "Electrically Induced Osteochondrogenesis" was solicited. These experts came to the conclusion that "non-invasive pulsing electromagnetic fields are both safe and effective in treating nonunion of long bones, failed fusion, and congenital pseudarthroses ... and that this treatment should be used only in cases unresponsive to conventional treatment modalities."

In February 1981, the HCFA Physicians Panel addressed the issue of **invasive** bone growth stimulators and the question of how nonunion should be defined. The Panel decided that HCFA should prepare a national instruction covering invasive stimulators, but only for nonunion of long bone fractures; nonunion to be defined as a fracture in which a minimum of six months had elapsed without healing. In October 1982 the Coverage Issues Manual 35-48 was revised to reflect these recommendations.

Following a manufacturer's request to expand the coverage of the direct current (invasive) stimulator as a surgical adjunct to enhance spinal fusion in 1990, the HCFA Physicians Panel suggested referral of the issue to the Office of Health Technology Assessments (OHTA).[4]

In May of 1994 the Technology Advisory Committee (TAC) suggested that CIM 35-48 be amended to include use of the invasive stimulator for extensive bone grafting for multiple level fusion and history of one or more previous failed spinal fusions. In addition, the TAC recommended that the definition of nonunion be changed to nine months of no healing from six months. This recommendation was based on FDA requirements for labeling of bone growth stimulators which stipulated that "nonunion is considered to be established when a minimum of nine months have elapsed since injury and the fracture site shows no visibly progressive signs of healing for a minimum of three months."

Following the TAC's recommendation, strong opposition from bone growth stimulator manufacturers and confusion caused by the discrepancy between HCFA national policy and the FDA labeling delayed revision of the manual. In June of 1996 the CIM was expanded to include (1) the use of invasive and noninvasive osteogenic stimulation as an adjunct to spinal fusion surgery for certain patients; and (2) clarification was added when noninvasive osteogenic stimulation is indicated after failed fusion ("where a minimum on nine months have elapsed since the last surgery"). No change was made in the definition of nonunion.

Recent Developments

On April 27 and 28th, 1999, the FDA's Orthopaedics and Rehabilitation Devices Advisory Panel met to discuss and make recommendations about a draft guidance document for bone growth stimulators FDA staff had prepared. The purpose of the FDA's guidance document was to update the original recommendations FDA had issued which helps guide manufacturers of bone growth stimulators in preparing investigational device exemption (IDE) and PMAs.

The panel heard presentations from several manufacturers of bone growth stimulators and had discussions which included the labeling issues regarding bone growth stimulators and the definition of nonunion. In conclusion, the panel recommended the removal of the "nine month" clinical study time frame from the definition of nonunion in bone growth stimulator labeling. Subsequent to this recommendation, FDA has granted approval to several bone growth stimulator manufacturers to change the labeling of their devices to read "nonunion is considered to be established when the fracture site shows no visibly progressive signs of healing." This change resulted from general agreement among panel members that the time frame definition for nonunion differed clinically from that of the original FDA document. According to FDA personnel, the original timeframe definition was essentially determined based on the need in clinical trials for patients to act as their own controls, and current clinical application of this timeframe were inappropriate (personal communication with Angel Torres-Cabassa, MD).

Formal Requests to HCFA Regarding Electrical Stimulation For Fracture Healing

HCFA is currently reviewing this issue at the request of two bone growth stimulator manufacturers, Orthologic, Inc., and EBI Inc.

Orthologic

Orthologic requests that HCFA revise its coverage policies regarding osteogenic stimulation to remove the current time frame limitation in defining when a nonunion is considered to exist. Orthologic based its request on the following points:

1. They assert that there is a significant body of published medical evidence favorably supporting the safety and efficacy of electromagnetic osteogenic stimulation in treating nonunion of bone fractures in a wide spectrum of patients.
2. FDA has changed the labeling to remove the time frame definition.
3. They assert that there is compelling post-marketing registry data that shows significant overall success rates involving a variety of bone fracture sites and high success rates for the elderly occurring with time from injury between 2 and 4 months.
4. There are over 80 third party payors that have adopted a policy covering the OL-1000 when used to treat nonunion of bone fractures with less than 6 months of evidence showing no progression in healing.

Orthologic has submitted material to HCFA staff during the course of this analysis (Appendix B). This material included:

- Peer-reviewed medical literature and clinical evidence
- Detailed analysis of Orthologic PMA data

- General and "patients over 65" registry data
- Third part payor policies regarding osteogenic stimulation

EBI

EBI requests that HCFA revise its coverage policies regarding osteogenic stimulation to remove the current time frame limitation as well as expand coverage to include all bones of the appendicular skeleton. EBI based its request on the following points:

1. They assert that Medicare coverage for bone stimulation is out of step with approved FDA labeling and the standard of care as used by today's orthopedic community.
2. They assert that Medicare's outdated policy will not cover necessary orthopedic conditions.
3. They assert that Medicare's national policy forces patients to surgery and prolonged disability.
4. They assert that Medicare's policy prevents any discretion by the Durable Medical Equipment Regional Carriers.

EBI has submitted and presented material to HCFA staff during the course of this analysis (Appendix B). This material included:

- Peer-reviewed medical literature and clinical evidence
- An analysis of Medicare data regarding bone grafting of nonunion fracture
- Detailed analysis of EBI PMA data
- An outcome assessment of patients 65 and older treated at periods earlier than 6 months post fracture
- Other third part payor policies regarding osteogenic stimulation

Timeline of Activities

On July 1, 1999, HCFA accepted Orthologic's formal request for revision of Medicare's national policy regarding osteogenic stimulation and notified the company of our intention to forward a response within 90 days. This request included the materials noted above.

On August 18, 1999, HCFA accepted EBI's formal request for revision of the same policy and notified both manufacturers that these requests were being combined so that a single decision could be made on this issue. Both companies were notified that a new 90 day time frame was initiated with the receipt and acceptance of a duplicate request. This request included the materials noted above.

HCFA staff engaged in significant dialogue with both manufacturers regarding their respective requests. Both companies also provided additional written information to HCFA throughout the course of the analysis and arranged conference calls to clarify details provided in their requests.

HCFA staff also supplemented the information provided by Orthologic and EBI by independently conducting a literature review, consulting experts in the field, and communicating with other manufacturers and specialty societies.

On October 13, 1999, representatives from EBI met with HCFA staff in Baltimore to present their materials.

Analysis of Scientific Data

A detailed analysis of the materials that HCFA staff critically evaluated can be found in Appendix A. These include unpublished registries as well as peer-reviewed, published scientific articles.

Currently, electrical stimulation for fracture healing is an accepted therapeutic modality in the treatment of long bone nonunions, although the point at which stimulators are applied, and with what other therapies they are used in conjunction with, remains controversial. Several studies published since HCFA's initial coverage determination was made have illustrated the clinical effectiveness of this therapy, and the purpose of this analysis was to determine whether there was clinical and scientific evidence to allow HCFA to revise coverage of electrical stimulation for fracture nonunions. In this regard, Coverage and Analysis staff have framed the following questions to serve as guidelines for evaluating this issue.

Questions Related to the Analysis

- From a clinical and scientific perspective, is there data to support a change in the time frame definition of nonunion?
- Is there significant clinical and scientific evidence to support the use of electrical bone growth stimulators for the treatment of nonunion for bones of the entire appendicular skeleton?
- Does the strict language of the national policy prevent clinical decision making which may improve clinical benefit to Medicare patients with established nonunions?

Time Frame Definition of Nonunion

Currently, the published literature is inconclusive with respect to a universally recognized time frame definition for nonunion. Various time frame definitions have been used to define nonunion. Campbell's Operative Orthopedics reports that "the time when a given fracture should be united cannot be arbitrarily set" but notes that "a fracture of the shaft of a long bone should not be considered a nonunion until at least 6 months after injury because often union requires more time…"[5] Adams and Hamblen states that "in adults, the time usually required for consolidation of a fractured long bone, in favorable conditions, is about 3 months, though in many cases it extends to 4 or 5 months, especially in the case of a large bone such as a femur. Other sources describe nonunion as "a lack of healing at 6 to 8 months."[6]

Orthologic submitted nearly 500 references gathered from a review of nonunion literature spanning the last three decades. This review included published articles, abstracts, presentations, and textbook citations regarding various nonunion definitions. From this review, it is clear that two different components are used to describe nonunion: 1) Time-referent descriptions that identify the time elapsed since injury, and/or 2) Radiographic accounts describing healing activity at the fracture site.

The Orthologic review stated that of the nonunion definition and descriptions included in their analysis, 36% of the articles cited identified a time equal to or less than six months post-fracture, 17% included descriptions of nonunions between six and nine months, and 47% described a time since injury of nine months or greater as their criteria for union classification. Of the 91 articles that identified a definition for nonunion, 19% used a lack of radiographic progression in their definition, with a minimum of three months with no progression toward healing as criteria.[7]

In three randomized double-blind clinical trials that have involved electrical stimulation for fracture healing,[8] Parnell and Simonis supplied no definition for nonunion, Borsalino's study used patients three days post intertrochantic osteotomy, and Sharrard's investigation determined nonunion by the presence of movement at the fracture site and radiologically by the presence of a fracture line. In an early case series by Bassett,[9] all patients had to have had no change in the clinical and radiographic features of the nonunion for a minimum of four months. In this study, Bassett defined delayed union as occurring when "no clinical or radiographic evidence of union at four to nine months after fracture." Nonunion was described as "a fracture that had not united by nine months after the fracture." A retrospective case series published by Brighton et al. in *Clinical Orthopaedics and Related Research* stated that "diagnosis of nonunion was made radiographically when no progressive signs of healing of the callus were seen during a three month period."[10]

Both EBI and Orthologic provided HCFA with unpublished patient registries which examined the "heal" rates of patients who had received electrical stimulation for various nonunions. This unpublished data indicated that success rates for patients with nonunions less than 6 months in duration were equal to if not better than those of patients who had nonunions older than 6 months. However, these registries do not equate to rigorously controlled scientific studies. The possible biases that exist in these types of registries make it difficult to make any statements about causality, and coverage NCDs cannot be based on these registries alone.

Further analysis by HCFA and discussions with the orthopedic community confirmed that there were no established criteria for determining when a fracture has reached a stage of nonunion. Most clinicians agreed that a strict time frame limitation for considering nonunion was unreasonable given the differing nature of fracture patterns and existing patient comorbidities. Many agreed that the 6 month limitation appeared arbitrary and was not based on the limited research there has been to date.

Because clinical indications of nonunion such as motion, pain, and tenderness at the fracture site are subjective measures which are difficult to validly and reliably measure, it is evident that radiographic studies over a fixed time period are a better indication of nonunion. Repeated AP and lateral images showing no progressive healing in a fracture over a three month period has become the standard which most large commercial payors use to define nonunion. Coupled with clinical evidence gathered from patient interview and examination, this radiographic evidence can provide a clinical picture of nonunion which requires further intervention. By revising our policy to better reflect current scientific evidence and clinical practice, we feel that shortening the time frame definition of nonunion will benefit those beneficiaries for which this device is necessary.

Electrical Stimulation for Nonunion Fractures in the Appendicular Skeleton Other Than Long Bones

There is limited scientifically valid evidence to support electrical stimulation for fracture nonunions in bones of the appendicular skeleton other than the long bones. Both the Sharrard and Parnell randomized double-blind studies related to tibial fractures only, and Borsalino et al. examined only intertrochantic osteotomies.

Bassett et al. found an overall heal rate of 77% in 1,007 patients with ununited fractures and 71 cases of failed fusion.[11] This case series involved patients from the US and international locations, with long bones representing 97% of the total ununited fractures treated (65% tibia). A follow up study of a subset of these patients published in the *Journal of Bone and Joint Surgery*[12] found a success rate of 87% in 125 patients with 127 tibial lesions. This study did not involve any fracture nonunions of other bones of the appendicular skeleton.

Another case series published by Dunn and Rush in the *Southern Medical Journal*[13] investigating PEMF technology found a success rate of 81%, with union determined by examining x-rays taken at 6 week intervals to evaluate healing. This study examined 35 nonunion patients, with the tibia, femur, and humerus representing 83% of all nonunions. Nonunions of the carpal navicular, metacarpal, and proximal phalanx of the thumb were reported in only 5 patients.

Garland et al. published results from a prospective non-randomized trial using PEMF therapy in patients who had established nonunions that underwent a bone grafting procedure or internal fixation.[14] Of the 181 subjects enrolled, 139 patients completed treatment (defined as use of a pulsed electromagnetic stimulation device for a minimum of eight hours per day for six months or until union). Of these 139 patients, the success rates in 13 patients (14 fractures) of those patients who averaged less than 3 hours of daily device use was found to be statistically different from those patients who underwent the entire course of treatment. The authors concluded that this difference implied a dosage threshold and excluded these patients from further analysis. Of the remaining 126 patients (135 fractures), only 34 fractures were classified as non-long bone (scaphoid, metatarsal, ankle fusion, other fusion, and "other.") Although heal rates in these bones ranged from 60% to 80%, these fractures represent only a small percentage of the total number of nonunions in this trial. Furthermore, the limited statistical analysis, no mention of an intent to treat analysis on the drop-outs, and no randomization or matching utilized in this study raises serious methodological questions.

Although Holmes[15] provided an analysis comparing his study to others involving surgical intervention, the nine Jones fractures with clinical and radiographic signs of delayed union and nonunion treated with PEMFs (resulting in a 100% heal rate) represent a very small sample size in an uncontrolled case series. Furthermore, of these nine patients, 5 were classified as having delayed union.

Beckenbaugh provided results of a case series in *Orthopaedic Transactions* describing 24 patients with 24 established nonunions of the scaphoid treated with electrical stimulation and casting.[16] In this series, 10 patients were treated in a short arm cast for a stimulation period of 2 to 9 months and 14 patients were treated in a long arm cast for a stimulation period of 4.5 to 6 months. Because the short arm casted group had an initial heal rate of less than 50%, a protocol change to a long arm cast for the remainder of treatment led to an eventual heal rate of 87% for the combined group. This was a short report without statistical analysis or any description of exclusion/exclusion criteria or patient characteristics.

Frykman et al. retrospectively reviewed 50 patients with nonunited schaphoid fractures treated with PEMFs from 1979-1984.[17] 44 patients were included in the analysis, which showed a heal rate of 80%. The study provided good analysis of the failures and also included follow-up to 33 months. However, patient selection and the possibilities of bias resulting from the uncontrolled nature of this review bring into question its validity.

Calandra et al.[18] provide a good review of schaphoid fractures, but other than concluding that under certain conditions a scaphoid nonunion "may effectively be treated with pulsed electromagnetic stimulation combined with cast immobilization," this article provided little comment or review about electrical stimulation for fracture healing in the rest of the appendicular skeleton.

Both EBI and Orthologic included unpublished patient registry data in their requests to HCFA. Although these registries were reviewed by HCFA staff as part of the overall analysis, this type of data alone is generally not adequate for us to use to make coverage NCDs. The possibilities for biases in these uncontrolled registries make it difficult to make any statements about causality, and therefore they cannot be relied upon to provide valid scientific data.

We recognize that it is difficult to perform controlled, prospective, randomized, double-blind studies of electrical stimulation vs surgery or other treatment modalities. Given this limitation, we carefully considered the studies presented, along with information gathered from the clinical community, in examining this issue. However, the quality and quantity of the evidence cited above is not enough for us to make a positive determination on expanding coverage of electrical bone growth stimulators to nonunions other than for long bones. Furthermore, because of the paucity of studies surrounding this therapy and its current application, the current policy restricting coverage of this device to only those indications outlined in the CIM is necessary for protecting the integrity of the Medicare program and ensuring that its beneficiaries receive the most appropriate care.

In conclusion, HCFA's analysis suggests that maintaining the current coverage limitation of electrical bone growth stimulators to long bones while shortening the time frame definition of nonunion is a reasonable and necessary action.

DECISION

Amend Coverage Issues Manual section 35-48 to include:

Fracture nonunion is considered to exist only when serial radiographs have confirmed that fracture healing has ceased for three or more months prior to starting treatment with the electrical osteogenic stimulator. Serial radiographs must include a minimum of two sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days.

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[1] Adams JC and Hamblen D. *Outlines of Fractures, Including Joint Injuries, 17th ed*. London: Churchill Livingston; 1999.

[2] Otter MW, McLeod KJ, and CT Rubin. Effects of Electromagnetic Fields in Experimental Fracture Repair. C*linical Orthopaedics and Related Research* 1998;355 Suppl :S90-104.

[3] Fitzsimmons RJ, Ryaby JT, Mohan S, et al. Combined Magnetic Fields Increase Insulin-Like Growth Factor-II in the TE -85 Human Osteosarcoma Bone Cell Cultures. *Endocrinology* 1995;136(7):3100-3106

[4] In its 1993 report "Osteogenic Bone Growth Stimulation as a Surgical Adjunct to Enhance Spinal Fusion", the OHTA stated that "limited data suggest that the implantable bone growth stimulator may be a useful surgical adjunct to enhance spinal fusion in some patients, such as those who have had previous fusion failure or have need for extensive bone grafting that require a multiple level fusion."

[5] LaVelle DG, Delayed Union and Nonunion of Fractures, in Canale TS, editor., *Campbell's Operative Orthopaedics*, 9th ed. St. Louis, Missouri: Mosby-Lifeline; 1998.

[6] Caputo AE. Healing of Bone and Connective Tissue, in Bronner F and Worrell RV, eds., *Orthopaedics: Principles of Basic and Clinical Science*. New York: CRC Press; 1999.

[7] Orthologic staff notes that a majority of these studies were investigations completed by Dr. Brighton based upon the FDA clinical trial data.

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[12] Bassett CA, Mitchell SN, and SR Gaston. Treatment of Ununited Tibial Diaphyseal Fractures with Pulsing Electromagnetic Fields. *Journal of Bone and Joint Surgery (American Volume)* 1982;63-A(4):511-523.

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[15] Holmes GB. Treatment of Delayed Unions and Nonunions of the Proximal Fifth Metatarsal with Pulsed Electromagnetic Fields. *Foot and Ankle International* 1994;15(10)552-559.

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[18] Calandra JJ, Goldner RD, and WT Hardaker. Scaphoid Fractures: Assessment and Treatment. *Orthopedics* 1992;15(8):931-937.

Back to Top